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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,910	06/10/2002	Helen Jennifer Clark	P07572US00/BAS	8926
881	7590	06/17/2004	EXAMINER	
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			KIM, VICKIE Y	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/088,910	<b>Applicant(s)</b> CLARK ET AL.	
	<b>Examiner</b> Vickie Kim	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6, 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election acknowledged*

Applicants' provisional election of the group I, claims 1-3, 5 and 7 with traverse is acknowledged. However, the argument for the traversal is not persuasive. Applicants traverse the restriction/election requirement on the grounds that the technical feature(i.e. silicone composition as recited in claim 1) is found to be novel and unobvious over the prior art of the record.

First of all, applicants are reminded that under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature which is referred to Annex B of Appendix A1 of the MPEP(Administrative Instructions under the PCT, "Unity of Invention"). **The express "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art."**(Rule 13.2). Unity exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding claimed special technical features. In this case, the corresponding technical feature shared by each invention is drawn to a silicone polymer composition(not method of treatment of scar nor medical applicator) which is comprising an effective amount of a silicone gum, a silicom fluid, a silicone wax and a volatile silicone fluid. As mentioned earlier, retroactive review of US5902592, makes clear that the groups I-II lack the same or corresponding special technical feature because the cited reference(s) appear to demonstrate that the claimed technical feature does not define a

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contribution which each of the inventions, considered as a whole, makes over the prior art. For instance, US5902592 suggests all the critical elements required for making said silicone polymer composition wherein the composition of US'592 is used for cosmetic product such as foundation cream, see column 2, lines 17-29 and examples. Accordingly, the prior art of the record supports restriction of the claimed subject matter in to the groups as mentioned immediately above.

For the reason set forth above, the restriction requirement is deemed to be proper and made FINAL.

### ***Status of Application***

The claims 1-9 are pending. Claims 1-3, 5 and 7 are elected and presented for the examination. All remaining claims are withdrawn from further consideration as being non-elected. The following rejections are made.

### ***Information Disclosure Statement(IDS)***

1. The listing of references in search report submitted is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glover (EP0638308A1) in view of Hasenoehrl et al(US 6093408).

The claims are directed to a method of topical scar treatment or prophylaxis using a medical applicator and/or packaging device containing a gel composition comprising a silicone gum(1-25wt%), a silicone fluid (1-40wt%), a silicone wax(1-35wt%) and a volatile silicone fluid(1-90wt%).

Glover (EP'308, hereafter) teaches a silicone emulsion gel composition for moisturizing skin, wherein said composition comprising an oil phase containing a volatile silicone fluid(page 4, lines 38-), a silicone wax(page 3, lines 39-46), a silicone gum(page 4, lines 23-37), and a non-volatile silicone fluids(page 4, lines

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1-22). EP'308 also teaches other silicone materials such as a siloxane polyether having formula (I) or (ii) as recited in pages 2-3. EP'308 further teaches emollient oils included in the oil phase(e.g. silicones such as non-volatile siloxane fluids and volatile fluids), see page 3, lines 39-57.

As to claim 2, EP'308 teaches the hydroxy terminated dimethylsilicone polymer used as silicone gum(about 10%), see page 4, line 25-30 and examples.

As to claim 3, EP'308 teaches non-volatile silicone fluids as a film former(about 1-20%) having a viscosity about 100-10,000 mm<sup>2</sup>/S(centistokes), see pages 3, line 58 - age 4, line 22 and page 5, line 48.

For instance, the non-volatile silicone and silicone gum in the oil phase are film formers. The non-volatile silicone have a viscosity 5-several million mm<sup>2</sup>/S(centistokes), whereas volatile silicone fluids have a viscosity in the range of less than 5 mm<sup>2</sup>/S(centistokes), see page 4.

EP'308 also teaches other silicone materials such as the siloxane polyether of formula (I) is referred to hereinafter as the EO/PO silicone surfactant that often formulated as a blend containing 80% of a volatile cyclic silicone such as octamethylcyclotetrasiloxane.

All the critical elements required by applicant's claims are taught except the scar treatment and packaging device.

Hasenoehrl et al(US'408, hereafter) teaches a method for treating/preventing acne and reducing acne lesions and the composition(active agents) required for the said treatment, see abstract and column 11, lines 65-67.

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US'408 teaches that silicone composition comprising about 01-15% of silicone fluids(see col. 4 thru col. 5, lines 27), about 0.1-10% of a silicone gum(see col. 4, lines 21-59) and about 0.1-10% of ethylene oxide/propylene oxide silicone copolymer, see abstract and examples. US'408 also teaches that silicone fluids are consisting of a mixture of both non-volatile fluids(e.g. polydimethylsiloxane, about 0.65-30000 cent. at 25°C) and volatile fluids.

Most importantly, US'408 teaches that the active agents listed above are critical elements of the patented composition and are required for the effective treatment for treating/preventing acne and reducing acne lesions, see column 11, lines 65-67.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to extend EP'308 teaching to benefit the skin not only by moisturizing skin but also by treating/preventing acne and acne lesions when EP'308 is incorporated by US'408 because US'408 supports the effectiveness of the silicon polymer composition of EP'308 wherein all the active agents required for acne treatment and acne lesion reduction are essentially same and included in the composition of both patent and instant application. The minor variations such as a packaging device or a medical applicator(e.g. roller-ball pen) in order to improve the convenience and the product appearance is considered to be well within the level of the ordinary skilled artisan and thus, obvious.

One would have been motivated to do so because it is always to desired to extend the therapeutic modalities to increase industrial applicability and market

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value, most of all, increase selection option to the users so that users can get the maximum benefit by enhancing the convenience(one step for all) and cost effective treatment. These cited references are particularly pertinent and relevant because all the claimed elements and their roles are well taught in the cited reference.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

5. Claims 1-3, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasenoehrl et al(US 6093408) in view of Bara et al(US5902592).

Hasenoehrl et al(US'408)'s teaching is mentioned immediately above.

Applicant's claims differ because they require silicon wax.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to add silicone wax into the silicone polymer composition of US'408 used effectively in the treatment and/or prophylaxis of scar because Bara et al(US'592, hereafter) teaches that the addition of silicon wax into skin composition containing all the essential active agents taught by the US'408. US'592 teaches a cosmetic skin composition comprising volatile and non-volatile oils, silicon gum and silicon wax wherein silicone wax, see example

1. US'592 further teaches the final product can be available in the form of a



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make-up product such as mascara, eye-shadow, see page 5, lines 5-12. The minor variations such as a packaging device or a medical applicator(e.g. roller-ball pen) in order to improve the convenience and the product appearance is considered to be well within the level of the ordinary skilled artisan and thus, obvious.

One would have been motivated to do so because addition of silicon wax would have effectively enhanced the quality of the cosmetic composition(e.g. good holdness, firmability) so that the industrial applicability and product appearance would have been improved.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579(fax: 571-273-0579). The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the

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status of this application or proceeding should be directed to the receptionist  
whose telephone number is 571-272-1600.

**VICKIE KIM**  
**PRIMARY EXAMINER**

Vickie Kim  
June 13, 2004  
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